

### **REMARKS**

This paper is in response to the Official Action dated February 12, 2003. Claims 12-13 were pending in the application and stand rejected. Claims 14-16 have been added herein. Therefore, claims 12-16 are pending after amendment.

Applicants wish to thank the Examiner for the in-person interview with Applicants' representative on May 21, 2003. The following constitutes Applicants' written statement in compliance with 37 C.F.R. § 1.133(b) and MPEP § 713.04: Applicants' representative and the Examiner discussed the claimed invention, the pending rejection, and the art cited by the Examiner. Applicants' representative and the Examiner could not reach agreement that the claims are not obvious over the cited art. The Examiner did agree that removal of the language "or the like" from claim 12 would overcome the pending rejection under 35 U.S.C. § 112.

Turning to the Official Action, claims 12-13 were rejected under 35 U.S.C. § 112, second paragraph. The Examiner states that the language "or the like" is indefinite. Although Applicants' disagree with the Examiner that the claim is indefinite (as pointed out in Applicants' previously filed appeal brief), the language has been removed from claim 12 and "a support" been substituted therefor. Applicants believe this addresses the Examiner's

concerns. However, Applicants' submit that this amendment was not made for reasons related to patentability, nor narrows the scope of the claims.

Claims 12 and 13 were also rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,436,072 to Kullas *et al* in view of U.S. Patent No. 5,304,163 to Bonnici *et al*. The Examiner contends that Kullas discloses all of the limitations of the claims 12 and 13 except for the spike being coated with a lubricant, which is disclosed by Bonnici. According to the Examiner, it would have been obvious to modify the spike of Kullas with a lubricant as taught by Bonnici.

Applicants respectfully traverse the rejection. Bonnici does not disclose "a spike being adapted to penetrate a fitting in said irrigation bag and coated with a lubricant" as claimed. Bonnici is directed to a device for penetrating the stopper of a "standard drug vial," which is described as an elastomer, *e.g.*, rubber. See Abstract; col. 3, lines 44-50. To this end, the device has a sharp cannula penetrating the vial stopper. *Id.* A lubricant can be used on the cannula. Col. 5, lines 19-20. However, this is a cannula to penetrate a drug vial stopper, not a spike to penetrate an irrigation bag.

This distinction is recognized by by Bonnici itself. Bonnici describes a flexible container 12 having two ports, one for connecting to the drug vial, and the other being an "administration port 24." Abstract; col. 3, lines 23-50. With respect to the administration port,

it has a "membrane (not shown) of standard construction which closes [it] off. Col. 3, lines 25-28. "A spike of a standard intravenous administration set (not shown) can be inserted into the tubing 26 which pierces the membrane" of the container 12. Col. 3, lines 28-30. Bonnici does not state that the spike may be lubricated. Thus, while Bonnici discloses lubricating a cannula for a drug vial stopper, it does not disclose lubricating a spike for an irrigation bag. As the cited art fails to disclose a limitation of the invention, it cannot render it obvious. See MPEP § 2143.03 (invention cannot be obvious when prior art lacks an element of the claims).

Nor does the prior art provide any suggestion or motivation to modify Kullas. See MPEP § 2143.01 (prior art must suggest or motivate modification). Nothing in the prior art recognizes or suggests that there is a disadvantage of unlubricated spikes with regard to friction during insertion into an irrigation bag. A rubber drug vial stopper is not the same as an irrigation bag. Applicants respectfully submit that the Examiner is improperly using Applicants' own disclosure recognizing the prior art's disadvantage and hindsight reasoning to reject the claims. See MPEP § 2145.X.A. (impermissible hindsight).

Indeed, in view of Bonnici's express teaching to lubricate the cannula, its conspicuous silence as to the spike would suggest to one of ordinary skill in the art that the spike should not be lubricated. Thus, Bonnici teaches away from the invention. MPEP § 2145

(invention not obvious if prior art teaches away it). Accordingly, claim 12 is not obvious and the rejection should be withdrawn.

Finally, claims 12 and 13 are provisionally rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 21-23 of co-pending application 09/668,178. Applicants submit that claims 21-23 of that application were cancelled by amendment filed January 23, 2003 and are no longer pending. As there are no longer "conflicting claims" between the applications, the rejection should be withdrawn. See MPEP § 804.I.B.

As claim 12 is patentable, claims 13-16, which depend therefrom, are also patentable. However, Applicants submit that these claims are independently patentable. Claim 14 recites that the lubricated spike still can support its weight and that of the flexible tubing. Nothing in the cited art suggests this. Claim 16 recites that the fitting comprises a membrane. As discussed above, Bonnici (and the other cited art) is completely silent about lubricating the spike to penetrate a membrane, as opposed to a rubber drug vial stopper.

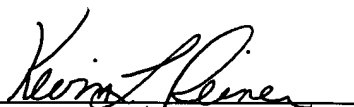
Applicants submit that in view of the amendments and remarks herein, the application is in condition for allowance, and such action is earnestly solicited. If there are any other issues remaining which the Examiner believes may be resolved through either a

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Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

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Respectfully submitted,



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